

# **EXHIBIT 3**

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## Inspections, Compliance, Enforcement, and Criminal Investigations

Kasa's Food Distributing Co. 7/5/12



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
PHILADELPHIA DISTRICT  
900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106  
Telephone: 215-597-4390

### WARNING LETTER 12-PHI-20

OVERNIGHT MAIL  
RETURN RECEIPT REQUESTED

July 5, 2012

Michael M. Kasapov, Owner  
Kasa's Food Distributing Co.  
3188 Shafers Schoolhouse Road  
Stroudsburg, PA 18360

Dear Mr. Kasapov:

The U.S. Food and Drug Administration (FDA) inspected your processing facility, located at 3188 Shafers Schoolhouse Road, Stroudsburg, PA on March 20, 2012 through March 28, 2012. Our inspection found significant deviations from the food labeling regulations, Title 21, Code of Federal Regulations (21 CFR), Part 101. These violations cause the your Frozen Sliced Red and Frozen Sliced White Pizza products, distributed by your firm to be misbranded within the meaning of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 343. You may find the Act and its implementing regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov)<sup>1</sup>.

Your significant violations are as follows:

1. Your Frozen Sliced Red Pizza product is misbranded within the meaning of section 403(w) of the Act, 21 U.S.C. § 343(w), in that the product label fails to identify the major food allergens wheat and milk for the Red Pizza as required by section 403(w)(1) of the Act.

Section 201(qq) of the Act, 21 U.S.C. § 321(qq), defines "major food allergens" as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans; as well as any food ingredient containing protein derived from one of these foods, with certain exceptions, e.g., highly refined oils derived from a major food allergen. A food is misbranded under section 403(w) of the Act if it is not a raw agricultural commodity and it is, or it contains, an ingredient that bears or contains, a major food allergen, unless either:

- The word "contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients, section 403(w)(1)(A) of the Act, 21 U.S.C. § 343(w)(1)(A); or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived (e.g., "Whey (Milk)"), except the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen), section 403(w)(1)(B) of the Act, 21 U.S.C. § 343(w)(1)(B).

2. Your Frozen Sliced Red Pizza and Frozen Sliced White Pizza products are misbranded under section 403(i)(2) of the Act, 21 U.S. C. § 343(i)(2) because they are fabricated from two or more ingredients but the label fails to bear the common or usual name of each ingredient. Specifically,

- Your Frozen Sliced Red Pizza and your Frozen Sliced White Pizza are made with **(b)(4)** flour and mozzarella cheese. The **(b)(4)** flour contains bleached wheat flour, malted barley flour, niacin, reduced iron, potassium bromate, thiamine mononitrate, riboflavin, and folic acid, and the mozzarella cheese contains pasteurized part skim milk, cheese cultures, salt and enzymes. Your label fails to declare many of these component ingredients.

According to 21 CFR 101.4(b)(2), the requirement to list these component ingredients (or "sub-ingredients") may be met by either (i) parenthetically listing the component ingredients after the common or usual name of the main ingredient, or (ii) by listing the component ingredients without listing the ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

- Your Frozen Sliced Red Pizza and your Frozen Sliced Red Pizza product label declares "sugar conditioners" as an ingredient. "Sugar Conditioners" is not an appropriate common or usual name under 21 CFR 101.4(a)(1).
- Your Frozen Sliced Red Pizza and your Frozen Sliced White Pizza product label declares "vegetable shortening" as an ingredient. "Vegetable shortening" is not an appropriate common or usual name under 21 CFR 101.4(b)(14) which requires that each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat," "cottonseed oil").
- Your Frozen Sliced Red Pizza and Frozen Sliced White Pizza are made with **(b)(4)** flour which appears to be a standardized flour, but your label fails to bear an appropriate common or usual name established under the flour standards in 21 CFR 137.

3. Your Frozen Sliced Red Pizza and Frozen Sliced White Pizza products are misbranded within the meaning of section 403(e)(1) of the Act [21 U.S.C. § 343(e)(1)] because the label fails to bear the place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5(a).

4. Your Frozen Sliced Red Pizza and Frozen Sliced White Pizza products are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. 343(q)] because the nutrition information on the label does not comply with the requirements in 21 CFR 101.9. Specifically,

- Your label declares the serving size as "1 slice"; however, the serving size in common household measure must be followed by the equivalent metric quantity in parentheses, as required by 21 CFR 101.9(b)(7).
- Your label does not contain a statement of the number of grams of trans fat in a serving or if a statement of the trans fat is not required your product does not contain the statement "Not a significant source of trans fat" at the bottom of the table of nutrient values [21 CFR 101.9(c)(2)(ii)]. More information regarding trans fat labeling can be accessed on our website at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053479.htm><sup>2</sup>

You should take prompt action to correct the violations described above. Failure to do so may result in regulatory action without further notice. Such action may include, but is not limited to, seizure or injunction.

Further, Section 743 of the Act, 21 U.S.C. § 379j-31, authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of there-inspection and assessing and collecting there-inspection fees, 21 U.S.C. § 379j-31(a)(2)(B). For a domestic facility, FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

In addition, we offer the following comments:

- Your Frozen Sliced Red Pizza and Frozen Sliced White Pizza product label fails to bear an accurate statement of the net quantity of contents in terms of weight, measure, or numerical count. Specifically, your product label incorrectly declares the net weight of your package as "4.5 oz. each." This is not an accurate statement of net weight because your package contains many slices of pizza.
- Your label fails to express cholesterol content to the nearest 5 mg increment, as required by 21 CFR 101.9(c)(3).
- The nutrition information on your label is presented in a tabular format. A firm may use a tabular or linear nutrition facts format if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape of size cannot accommodate a standard vertical column or tabular display on any label panel [21 CFR 101.9G)(13)(i)(B)]. In addition, the tabular display format may be used if there is not sufficient continuous vertical space (i.e. approximately 3 in.) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron [21 CFR 101.9(d)(II)(iii)]. If your packaging fails to meet one of these conditions, you are not eligible to use the tabular display for nutrition information.
- We also note that the informational brochure distributed by your sales representative declares different ingredients than those declared on your product label. Your product labeling should contain an accurate declaration of the ingredients actually used to manufacture your products in accordance with 21 CFR 101.4.
- We acknowledge that you provided our investigator with a draft revised label for your Regular Crust Red Pizza, Regular Crust White Pizza and Whole Wheat Crust Red Pizza. Our investigator informed you that this label failed to contain an ingredient statement, and you informed our investigator that due to lack of space, it would be difficult to include the ingredient statement as part of your labeling. This is not acceptable, and your products must contain ingredient labeling in accordance with 21 CFR 101.4.
- Our investigator was informed that you manufacture several sizes of red and white pizza to include 8", 12", 14", 16", 18", and 12" x 18" Sicilian pizza. Further, your firm stated that in a cost saving effort, only one (1) box is used by the firm which contains the same Nutrition Facts labeling, no matter what type or size pizza is placed in the box. Our investigator informed you that based on this, the Nutrition Facts information may not be accurate and that the new labeling only lists Nutrition information for the 18" pizza. This is not acceptable and the Nutrition Facts must be representative of what is contained in that product, as required by 21 CFR 101.9.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific things that you are doing to correct the violations described above. Include in your response documentation to show that correction has been achieved. If you cannot complete all corrections before you respond, state the reason for the delay and when you will complete the corrections.

This letter may not list all the violations in your product labeling or at your facility. You are responsible for ensuring that your firm operates in

compliance with the Federal Food, Drug, and Cosmetic Act and all applicable regulations. You are also responsible for ensuring that all of your products and their labeling are in compliance with the laws and regulations enforced by FDA. In addition to consulting the Act and Title 21 of the CFR, further guidance and information on food allergens can be accessed on FDA's website at:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm><sup>3</sup> and <http://www.fda.gov/Food/FoodSafety/FoodAllergens/default.htm><sup>4</sup>.

Your response should be sent to Lynn S. Bonner, Compliance Officer at the address noted above. If you have any questions with regard to this letter, Ms. Bonner can be reached at 215-717-3074 or [Lynn.Bonner@fda.hhs.gov](mailto:Lynn.Bonner@fda.hhs.gov).

Sincerely,  
/S/  
Kirk Sooter  
District Director  
Philadelphia District

#### Close Out Letter

- [Kasa's Food Distributing Co., Inc. - Close Out Letter 12/11/2012](#)<sup>5</sup>

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